



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that UNITUXIN (dinutuximab), manufactured by United Therapeutics Corporation, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4842, FAX: 301-796-9858, email:

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SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), added by FDASIA, FDA will award priority review vouchers to

sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that UNITUXIN (dinutuximab), manufactured by United Therapeutics Corporation, meets the criteria for a priority review voucher. UNITUXIN (dinutuximab) is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy. Neuroblastoma is the most common pediatric solid tumor occurring outside the brain, and it is the most common cancer in infants.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>.

For further information about UNITUXIN (dinutuximab), go to the Drugs@FDA Web site at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>.

Dated: April 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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